

## § 20.44

## 21 CFR Ch. I (4–1–15 Edition)

(e) If a request does not qualify for the fastest processing track, the requester may be provided an opportunity to limit the scope of the request in order to qualify for faster processing.

[68 FR 25286, May 12, 2003]

### § 20.44 Expedited processing.

(a) The Food and Drug Administration will provide expedited processing of a request for records when the requester demonstrates a compelling need, or in other cases as determined by the agency. A compelling need exists when:

(1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.

(b) A request for expedited processing made under paragraph (a)(1) of this section must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or other authorized representative of the individual, and must demonstrate a reasonable basis for concluding that failure to obtain the requested records on an expedited basis could reasonably be expected to pose a specific and identifiable imminent threat to the life or safety of the individual.

(c) A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:

(1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;

(2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and

(3) The request for records specifically concerns identifiable operations

or activities of the Federal Government.

(d) All requests for expedited processing shall be filed in writing as provided by § 20.40. Each such request shall include information that demonstrates a reasonable basis for concluding that a compelling need exists within the meaning of paragraph (a) of this section and a certification that the information provided in the request is true and correct to the best of the requester's knowledge and belief. Any statements made in support of a request for expedited processing are subject to the False Reports to the Government Act (18 U.S.C. 1001).

(e) The Assistant Commissioner for Public Affairs (or delegatee) will determine whether to grant a request for expedited processing within 10 days of receipt by the Division of Freedom of Information of all information required to make a decision.

(f) If the agency grants a request for expedited processing, the agency shall process the request as soon as practicable.

(g) If the agency denies a request for expedited processing, the agency shall process the request with other non-expedited requests.

(h) If the agency denies a request for expedited processing, the requester may appeal the agency's decision by writing to the official identified in the denial letter.

[68 FR 25286, May 12, 2003, as amended at 76 FR 31469, June 1, 2011]

### § 20.45 Fees to be charged.

(a) *Categories of requests.* Paragraphs (a) (1) through (3) of this section state, for each category of request, the type of fees that the Food and Drug Administration will generally charge. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given in paragraphs (b) and (c) of this section and in § 20.46 or for other reasons.

(1) *Commercial use request.* If the request is for a commercial use, the Food and Drug Administration will charge for the costs of search, review, and duplication.

(2) *Educational and scientific institutions and news media.* If the request is from an educational institution or a